Purged by L. Davis 7/13/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

T1928M

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JUL 10 1998

WARNING LETTER
98-DT-15

Klaus Julicher, President and CEO
Schwarz Pharma US Operations
6140 W. Executive Drive
Mequon, WI 53092

Dear Mr. Julicher:

Investigators Steven Eastham, Michael Sheehan, Charlie Hoppes, and Chemist Kenneth Scholz inspected Schwarz Pharma Manufacturing, Inc. [SPMI] Seymour, IN from April 21-May 22, 1998. They found the firm to be operating with significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211]. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

> Production and process control procedures for sustained release capsules are not designed to assure that each batch will have the quality and purity it purports to have in that sustained release beads do not have consistent in-process test results within batches and between batches of the same formulation/process. [21CFR 211.100(a)]

We acknowledge receipt of your June 2, 1998 response letter to the FDA 483 issued to your firm on May 22, 1998 and June 16, 1998 SPMI Investigation Report regarding product verification testing. We also thank your representatives for coming to Detroit to discuss the inspectional findings during a June 12, 1998 meeting with Compliance Officer Judith A. Putz. The corrections promised in your firm's letters and meeting discussion have been made a part of the SPMI Seymour, IN file and will be evaluated during the next inspection.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Failure to take corrective action may result in regulatory action without further notice. Possible actions include seizure and/or injunction. Federal agencies are advised on the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office in writing, within 15 working days of your receipt of this letter, of any additional steps your have taken to correct the matters discussed in this letter.
Your reply should be sent to the Food and Drug Administration, Detroit District Office, 1560 East Jefferson Avenue, Detroit, MI 48207, Attention: Judith A. Putz, Compliance Officer.

Sincerely,

John P. Kempster

Raymond V. Mlecko
for Acting District Director
Detroit District

Enclosure: FDA 483 - May 22, 1998

cc: John R. Lee
Vice President, Pharmaceutical Operations
Schwarz Pharma Manufacturing, Inc.
P.O. Box 328
Seymour, IN 47274